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APPLICATION NUMBER: *60/417,408*
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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. EV049330651US

INVENTOR(S)

Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Petrus A.	Besselink	The Netherlands

☐ *Additional Inventors are being named on the _____ separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

VASCULAR FILTER WITH IMPROVED STRENGTH AND FLEXIBILITY

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ENCLOSED APPLICATION PARTS *(check all that apply)*

☒ Specification *Number of Pages*	10	☐ CD(s), Number	
☒ Drawing(s) *Number of Sheets*	3	☐ Other (specify)	
☒ Application Data Sheet. See 37 CFR 1.76			

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☒ Applicant claims small entity status. See 37 CFR 1.27.

☒ A check or money order is enclosed to cover the filing fees

☐ The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number. _____

☐ Payment by credit card. Form PTO-2038 is attached.

FILING FEE AMOUNT ($): 80.00

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No

☐ Yes, the name of the U S Government agency and the Government contract number are: _____

Respectfully submitted,

SIGNATURE _____

TYPED or PRINTED NAME John D. Reed

TELEPHONE (937) 223-2050

Date 10/9/02

REGISTRATION NO. *(if appropriate)* 46,506

Docket Number: BES 0009 M2

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

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FEE TRANSMITTAL for FY 2002

Patent fees are subject to annual revision

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 80.00

Complete if Known	
Application Number	
Filing Date	October 9, 2002
First Named Inventor	Petrus A. Besselink
Examiner Name	
Group Art Unit	
Attorney Docket No.	BES 0009 M2

METHOD OF PAYMENT *(check all that apply)*

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FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
101	740	201	370	Utility filing fee	
106	330	206	165	Design filing fee	
107	510	207	255	Plant filing fee	
108	740	208	370	Reissue filing fee	
114	160	214	80	Provisional filing fee	80.00

SUBTOTAL (1) ($) 80.00

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

		Extra Claims		Fee from below		Fee Paid
Total Claims		-20** =		x	=	
Independent Claims		- 3** =		x	=	
Multiple Dependent					=	

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
103	18	203	9	Claims in excess of 20
102	84	202	42	Independent claims in excess of 3
104	280	204	140	Multiple dependent claim, if not paid
109	84	209	42	** Reissue independent claims over original patent
110	18	210	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) 0.00

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FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
105	130	205	65	Surcharge - late filing fee or oath	
127	50	227	25	Surcharge - late provisional filing fee or cover sheet	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request for *ex parte* reexamination	
112	920*	112	920*	Requesting publication of SIR prior to Examiner action	
113	1,840*	113	1,840*	Requesting publication of SIR after Examiner action	
115	110	215	55	Extension for reply within first month	
116	400	216	200	Extension for reply within second month	
117	920	217	460	Extension for reply within third month	
118	1,440	218	720	Extension for reply within fourth month	
128	1,960	228	980	Extension for reply within fifth month	
119	320	219	160	Notice of Appeal	
120	320	220	160	Filing a brief in support of an appeal	
121	280	221	140	Request for oral hearing	
138	1,510	138	1,510	Petition to institute a public use proceeding	
140	110	240	55	Petition to revive - unavoidable	
141	1,280	241	640	Petition to revive - unintentional	
142	1,280	242	640	Utility issue fee (or reissue)	
143	460	243	230	Design issue fee	
144	620	244	310	Plant issue fee	
122	130	122	130	Petitions to the Commissioner	
123	50	123	50	Processing fee under 37 CFR 1 17(q)	
126	180	126	180	Submission of Information Disclosure Stmt	
581	40	581	40	Recording each patent assignment per property (times number of properties)	
146	740	246	370	Filing a submission after final rejection (37 CFR § 1.129(a))	
149	740	249	370	For each additional invention to be examined (37 CFR § 1.129(b))	
179	740	279	370	Request for Continued Examination (RCE)	
169	900	169	900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid **SUBTOTAL (3)** ($) 0.00

SUBMITTED BY				Complete *(if applicable)*	
Name (Print/Type)	John D. Reed	Registration No (Attorney/Agent)	46,506	Telephone	(937) 223-2050
Signature				Date	October 9, 2002

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Initial Information Data Sheet

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Application Information

Title Line One::	VASCULAR FILTER WITH IMPROVED STRENGTH
Title Line Two::	AND FLEXIBILITY
Total Drawing Sheets::	3
Formal Drawings?::	Yes
Application Type::	Provisional
Docket Number::	BES 0009 M2

Representative Information

Registration Number One::	26,397
Registration Number Two::	27,262
Registration Number Three::	29,001
Registration Number Four::	39,564
Registration Number Five::	38,769
Registration Number Six::	33,758
Registration Number Seven::	42,695
Registration Number Eight::	46,867
Registration Number Nine::	46,506
Registration Number Ten::	46,458
Registration Number Eleven::	48,624
Registration Number Twelve::	52,364

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of

Applicants : Petrus A. Besselink

Title : VASCULAR FILTER WITH IMPROVED STRENGTH AND FLEXIBILITY

Docket No. : BES 0009 M2

BOX PROVISIONAL PATENT APPLICATION
Assistant Commissioner for Patents
Washington, DC 20231

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Melody J. Tolliver
Legal Secretary

JDR/kec

Provisional Patent Application Enschede, October 8, 2002 **Confidential !!!**

Vascular filter with improved strength and flexibility

Inventor: (Citizen of The Netherlands).

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Abstract:

This invention relates to membranes for vascular filters with improved strength and flexibility compared to the filters that are now on the market. The filters make use of a proximal frame section and a distal section, made of a flexible thin membrane with perfusion holes of a diameter that allows blood to pass, but prevents the movement of emboli downstream. Both can be collapsed into a small diameter delivery catheter and expanded upon release from this catheter. The distal filter membrane has a proximal entrance mouth, which has almost the same size as the body lumen. It is attached to the proximal section, which has the function to keep the mouth of the distal filter open and prevent the passing of emboli between the body lumen wall and the edge of the filter mouth. In order to have a good flexibility the membrane is made extremely thin. Normally this would create the risk that the membrane could tear easily, which could cause big problems because emboli and pieces of the membrane would then be taken downstream from the filter site. This problem is overcome by embedding the filter membrane with thin filaments of a material with high strength in longitudinal direction, but high flexibility upon bending Such a composite filter membrane can have extreme flexibility and elasticity in certain directions, combined with limited deformation, high strength and prevention of crack propagation through the membrane material. Further the filaments can be attached to the proximal frame in such a way that the connection points act as hinges and as additional safety for the case that the membrane material might come loose from the frame. Another function of the embedded filaments is that they help to give the membrane a desired shape after deployment. A method for producing such filters is also disclosed. Fibers are not only used as reinforcement for the membranes, but are also used as pull wires for the retrieval of an expandable frame into a removal sheath. Such frames can be used in temporary devices like a removable temporary stent, dilator, reamer, occlusion device for main artery or side artery, a housing for a graft, a valve, a delivery platform for drugs, radiation or gene therapy or any other device that has to be placed and removed after some time. Applications are not restricted to arteries, but are meant for all body lumens.

The reinforced membranes can also be used for parts of catheters, like for example inflatable parts, balloon pumps, replacement of body tissues, repair of body parts and functional parts like artificial valves and membranes.

Background of the invention

This application relates to the field of producing an expandable frame with a membrane that is placed in a body lumen, like for example an improved distal filter for protection against emboli, which can migrate during angioplasty/stenting procedures.

In US provisional application 09/803,641 and US 2001/0044634 A1 a double filter system was described with a distal filter and a second, proximal filter that closes the entrance of the distal filter before it is collapsed in order to be removed.

In US 5,885,258 a retrieval basket for catching small particles was disclosed, made from a slotted nitinol tube. The pattern of the slots allows expansion of the nitinol basket and by shape setting (heat treatment in the desired unconstrained geometry) this basket is made expandable and collapsible by means of moving it out or into a surrounding delivery tube.

In principle a distal filter is made of such an expandable frame that defines the shape and enables placement and removal, plus a filter membrane or mesh that does the actual filtering work.

Sometimes the expandable frame and the mesh are integrated and made from a single material, for example Nitinol, like in US 6,383,205 or US 2002/0095173. These filters do not have a well-defined and constant size of the holes where the blood flows through, because of the relative movement of the filaments in the mesh. This is a disadvantage, because the size of emboli can be very critical, e.g. in procedures in the carotid arteries. Further the removal of such a filter, accompanied by a reduction of the diameter, may be critical because emboli can be squeezed through the mesh openings with their changing geometry.

A much better control of the particle size is achieved with a separate membrane or filter sheath, which has a well-defined hole pattern with for example holes of 100 microns, attached to a frame that takes care of the correct placement and removal of the filter. In WO 00/67668 a Nitinol basket forms the framework of the filter, and a separate polymer sheath is attached around this frame. At the proximal side the sheath has large entrance ports for the blood and at the distal side a series of small holes filters out the emboli. This system, however, has some major disadvantages. First of all, the closed basket construction makes this filter frame rather rigid and therefore it is difficult to be used in strongly tortuous arteries. In a curve it may even not fit well against the artery wall and cause leakage along the outside of the filter. Another disadvantage of such filters is there is a high risk of squeezing-out the caught debris upon removal, because the struts of the framework force the debris back in proximal direction, while the volume of the basket frame decreases when the filter is collapsed. Further the construction makes it very difficult to reduce the profile upon placement of the filter. This is very critical, because these filters have to be advanced through critical areas in the artery, where angioplasty and/or stenting are necessary. Of course the catheter that holds this filter should be as small as possible then. In the just described filter the miniaturization will be difficult, because at a given cross section there is too much material. The metal frame is surrounded by polymer and in the center there is also a guide wire. During angioplasty and stenting the movements of the guide wire will further create forces, which influence the position and shape of the filter, which may cause problems with the proper sealing against the artery wall. This is also the case in strongly curved arteries. It would be good if the guide wire could freely move in tangential, axial, and radial direction through the cross section area where the filter is placed, without influencing the position and shape of the filter.

In US 6,348,062 the frame is placed proximal and the distal polymer filter membrane has the shape of a bag, attached to one or more frame loops, forming an entrance mouth for the distal filter bag. Here the bag is made of a very flexible polymer and the hole size is well defined. Upon removal the frame is closed, thus closing the mouth of the bag and partly preventing the squeezing-out of debris. This is already much better than for the full basket design, which was described above, where the storage capacity for debris of the collapsed basket is relatively small. The filter bag is attached to the frame at its proximal end and sometimes to a guide wire at its distal end. Attachment to the guide wire can be advantageous, because some pulling force may prevent bunching of the bag in the delivery catheter. It may be clear that it is easier to pull a flexible folded bag through a small diameter hole, than to push it through. However, the deformation of the bag material should stay within certain limits, and it would be excellent if these limits would be controllable. If the filter is brought into a delivery sheath of small diameter, collapsing the frame and pulling the bag into the delivery sheath causes rather high forces on the connection sites of filter to frame and/or guide wire. While the metal parts of the frame slide easily through such a delivery sheath, the membrane material may have the tendency to stick and in the worst case it may even detach from the frame, tear upon placement or during use, just because of too much friction, unlimited expansion, crack propagation etc. The connection of the filter bag to the frame is rather rigid, because of the method of direct attachment. Additional flexibility, combined with a high strength attachment spot would also be advantageous. To overcome the strength problem, the membrane may be made thicker, but this makes the overall size also larger and thus the crossing profile. If the membrane is relatively thick, the blood flow through the holes will of course also be less than in the case where the holes are made in an extremely thin membrane.

Methods for making kink resistant reinforced catheters by embedding wire ribbons are described in PCT/US93/01310. A mandrel is coated with a thin layer of encapsulating material. Than a means (e.g. a wire) for reinforcement is deposited around the encapsulating material and eventually a next layer of encapsulating material is coated over the previous layers, including the reinforcement means. Finally the mandrel is removed from the core of the catheter. Materials for encapsulating are selected from the group consisting of polyesterurethane, polyetherurethane, aliphatic polyurethane, polyimide, polyetherimide, polycarbonate, polysiloxane, hydrophilic polyurethane, polyvinyls, latex and hydroxyethylmethacrylate. Materials for the reinforcement wire are stainless steel, MP35, Nitinol, tungsten, platinum, kevlar, nylon, polyester and acrylic. Kevlar is a Dupont product, made of long molecular higly oriented chains, produced from poly-paraphenylene terephalamide. It is well known for its high tensile strength and modulus of elasticity.

In US 09/537,461 the use of polyethylene with improved tensile properties is described. It is stated that high tenacity, high modulus yarns are used in medical implants and prosthetic devices. Properties and production methods for polyethylene yarns are disclosed.

US 5,578,374 describes very low creep, ultra high modulus, low shrink, high tenacity polyolefin fibers having good strength retention at high temperatures and methods to produce such fibers. In an example the production of a poststretched braid, applied in particularly woven fabrics is described.

In US 2001 0034197 oriented fibers are used for reinforcing an endless belt, comprising a woven or non-woven fabric coated with a suitable polymer of a low hardness polyurethane membrane, in this case to make an endless belt for polishing silicon wafers. Examples are mentioned of suitable yarns like meta- or para-aramids such as KEVLAR, NOMEX OR TWARON; PBO or its derivatives; polyetherimide; polyimide; polyetherketone; PEEK; gel-spun UHMW polyethylene (such as DYNEEMA or SPECTRA); or polybenzimidazole; or other yarns commonly used in high-performance fabrics such as those for making aerospace parts. Mixtures or blends of any two or more yarns may be used, as may glass fibers (preferably sized), carbon or ceramic yarns including basalt or other rock fibers, or mixtures of such mineral fibers with synthetic polymer yarns. Any of the above yarns may be blended with organic yarns such as cotton.

Disclosure of reinforcement of thin membranes with fibers for the use in filters is not found in the known literature.

Summary of the invention

This invention relates to vascular filters with improved strength and flexibility compared to the filters that are now on the market. The filters make use of a proximal and a distal section, which can be collapsed into a small diameter delivery catheter and expanded upon release from this catheter. The proximal section is made as a frame of a relatively rigid material, for example a metal and the distal section is made of a flexible thin membrane with perfusion holes of a diameter that allows blood to pass, but prevents the movement of emboli downstream. The distal filter membrane has a proximal entrance mouth, which has almost the same size as the body lumen. It is attached to the proximal section, which has the function to keep the mouth of the distal filter open and prevent the passing of emboli between the body lumen wall and the edge of the filter mouth. In order to have a good flexibility and a minimized crossing profile upon delivery the membrane is made extremely thin. Normally this would create the risk that the membrane could tear easily, which could cause big problems because emboli and pieces of the membrane would then be taken downstream from the filter site. This problem is overcome by embedding the filter membrane with thin filaments of a material with high strength in longitudinal direction, but high flexibility upon bending. Such a composite filter membrane can have extreme flexibility and elasticity in certain directions, combined with limited deformation, high strength and prevention of crack propagation through the membrane material. Further the filaments can be attached to the proximal frame in such a way that the connection points act as hinges and as additional safety for the case that the membrane material might come loose from the frame. Another function of the embedded filaments is that they help to give the membrane a desired shape after deployment. The surface of the membrane filter may be coated with some additional material that improves the properties, for example the biocompatibility, drugs release or any other desired property, which the membrane itself does not offer. Another object of the invention is that the reinforced membranes can also be used for parts of catheters, replacement of body tissues, repair of body parts and functional parts like artificial valves and membranes, where minimal thickness and/or high strength are required.

Fibers are not only used as reinforcement for the membranes, but are also used as pull wires for the retrieval of an expandable frame into a removal sheath. Such frames can be used in temporary devices like a removable temporary stent, dilator, reamer, occlusion device for main artery or side artery, a housing for a graft, a valve, a delivery platform for drugs, radiation or gene therapy or any other device that has to be placed and removed after some time. Applications are not restricted to arteries, but are meant for all body lumens.

Further a method for producing filters by dipping on a removable mold is disclosed.

Detailed description of the invention

The advantages of the invention will become more apparent after reference to the following description, wherein some embodiments are elucidated.

In the present invention a filter with improved flexibility and smaller profile is described. The filter basically has a proximal frame for expansion and contraction and attached thereto a thin filter bag which basically exists out of minimal two materials. One material is the highly flexible filter membrane itself, with a pattern of holes for allowing flow of blood particles below a well defined size, and the other material is a reinforcement made of fine fibers with high axial strength but thin enough to be flexible upon bending. The reinforcement is integrated with the membrane to create a composite structure with very flexible membrane areas where the blood is filtered and extremely strong reinforcement fibers that take up excessive forces, control the shape of the filter and act as flexible hinges at the points of attachment to the proximal frame and/or the guide wire. These fibers can be embedded in the membrane by a dipping or spraying process or they can be attached with glue, stitching, a solvent for the membrane material, heat, welding etc. In order to get a better connection between the reinforcement fibers and the membrane material the fibers may first be coated with a material that adheres well to the membrane material, for example with the same material. Fibers can be made of any strong and tough material, preferably a material with a modulus of elasticity that is much higher than for the surrounding membrane. It can be made of round, flat or different shaped mono-filaments or multi-filaments and it can be based on metal, for example titanium or Nitinol, carbon, boron, glass, or polymers, for example ultra high molecular weight polymers with extreme tensile strength and high modulus. The fibers not only reinforce the membrane, but also can be used to control the final geometry, stop crack propagation, act as hinges at the place of attachment to the frame and prevent loss of the membrane or parts of it. Because of the reinforcement the membrane itself can be made much thinner, so the crossing profile of the composite filter can be much lower than for a single polymer membrane, even if the reinforcement fibers are much thicker than the membrane itself.

A method for making such a reinforced filter is also disclosed. A paraffin mold is prepared into the desired shape of the filter bag and than it is provided with a polymer skin, which easily detaches from the membrane polymer. This paraffin mold is dipped in a solution of polymer and solvent until a layer of membrane polymer is created. After that step the mold is attached to the frame and the coated reinforcement fibers are than mounted to the frame at the hinge sites and laid over the surface of the mold. Another dipping step then ensures full embedding of the fibers into the growing membrane polymer layer. Finally the hole pattern is laser drilled into the membrane and the last step is the removal of the paraffin by melting it out in warm water. The polymer skin easily detaches from the inside of the filter membrane and is pulled out. With the use of a paraffin mold it is possible to make complicated or very simple designs, because there is no need to remove a relatively large mandrel from the filter after it has been made. This would be complicated if the mandrel was for example a metal or polymer part, which had to be pulled through some openings at the proximal side. Paraffin is of course not the only material that can be used for a mold. Any material that can be brought into the desired shape and which can be directly dipped or with an intermediate layer may be used. Examples are meltable materials or materials that easily dissolve in water, like salt or sugar crystals. Other examples are fine grains in a vacuum bag or a inflated balloon which is deflated after dipping.

Fibers are also used for enabling the removal of expandable devices by means of pulling them into a removal sheath.

Description of the drawings

The principles of the disclosed invention become clear in the following description of the figures. Identical parts in different figures are mentioned with the same number.

The principles of the disclosed invention become clear in the following description of the figures. Identical parts in different figures are mentioned with the same number.

Figure 1 shows a paraffin mold 1, made in the desired filter shape. Paraffin is chosen, because it can be removed from the filter easily, at a temperature that does not cause degradation of the polyurethane of the filter. However, dipping of polyurethane directly to the paraffin is not giving good results and a thin layer of polyvinylalcohol 2 surrounds therefore this paraffin mold. The polyvinylalcohol is a thin sheet that can be stretched after wetting with water and pulled tight around the paraffin and then tied together with a small clip or wire 3. Than it is dipped a few times in a solution of polyurethane in tetrahydrofuran, thus building a layer of polyurethane of e.g. 3 microns at the right side of the dipping line.

Figure 2 gives a nitinol frame 20, made from tubing with outer diameter 0.8 mm by laser cutting and shape setting. At the proximal side, which is on the left, the tube end 25 is uncut and still 0.8 mm. in diameter. From there eight longitudinal spokes 26 run until they end in a zigzag section with struts 27, where the unconstrained,

expanded diameter is 8 mm at its largest size. This frame 20 will, at any size between the maximum diameter and the collapsed size of 0.8mm diameter, always adapt smoothly to the given geometry of the artery. In this frame the mold of figure 1 is placed and eight wires of a reinforcement fiber 28 of for example multifilament ultra high molucular weight polymer are attached to the most distal section of the nitinol frame 20 at points 29. These fibers can be attached to the nitinol by means of a knot or they can just be wrapped around the nitinol struts and run back and forth from the distal tip to the strut ends 29. At the distal tip all fibers come together in a guide ring or tube 30, where they are held in correct position for the further dipping.

Figure 3 shows how the mold with the nitinol frame and the surrounding fibers have been dipped a few more times until the fibers are well embedded in the polyurethane, for example until the layer polyurethane is 5 microns thick at the places 31 where no reinforcement fibers 28 are. Of course the thickness at the places 32, where these fibers are, is larger than at places 31, dependent of the type of fibers and the amount of dipping steps. Guide tube 30 of figure 2 has been removed after the dipping was finished and the membrane was dry.

Figure 4 shows the final filter 40, with a pattern of holes 41 of 100 micron diameter, which has been has been laser drilled between the reinforcement fibers 28 and after that the central paraffin mold has been removed by melting in warm water of 50 degrees celsius. The polyvinylalcohol layer easily released from the polyurethane filter membrane and was removed. Further the fibers 28 have been cut to the correct length at point 42 and attached to the central guide wire 43 in a nose tip 44 that fits on top of the delivery catheter if the filter is withdrawn into this catheter before placement into the body lumen of the patient. Note that the polyurethane between the nitinol struts was also removed at the proximal side of the struts 27, preferably by laser cutting.

This construction is extremely strong and still very flexible. The 5 microns thick membrane with the reinforcement fibers 28 fits easily in a delivery catheter of only 0.9 mm inner diameter and adapts to all sizes of arteries between 1 and 8 mm diameter. The central guide wire 43 helps to pull the filter membrane out of the delivery catheter, and all tension force is taken up by the reinforcement fibers 28. The membrane only has to follow these fibers and unfold as soon as it leaves the catheter. The filter opens because of the elasticity of the nitinol frame and also because the blood pressure even helps it further to open like a parachute. Upon bending there is almost no force needed at the sites where fibers are attached to the nitinol struts, so these sites act as hinges. Even in strongly curved arteries the filter frame still adapts well to the wall and there is almost no blood leaking between membrane and artery wall. The fibers are so well embedded in the polyurethane, that in case the polyurethane detaches from the nitinol struts, the membrane will still have a strong connection to the frame and can be collapsed and removed from the patient safely. In case of a tear in the membrane, for example starting from a 100 micron hole, this membrane may tear further, but only until the crack meets a fiber. There the crack will stop, and the membrane can be removed safely and completely as well. (Of course this situation is very undesirable and the loss of some entrapped emboli may be the consequence, but at least the removal of the filter itself does not cause problems). After the procedure the nitinol frame can be collapsed to close the mouth of the filter and entrapped emboli can not leave this closed filter bag anymore. The hinges guarantee now that the filled bag hangs at the distal end of the removal catheter and still can move easily through curved arteries.

The reinforcement wires are not only used for their high tensile strength. Nitinol wires can be shape set to almost any desired shape by heat treatment. Such wires may be embedded in or attached to the membrane to guarantee a smooth folding/unfolding of the membrane. An example is an embedded nitinol wire that helps to give the mouth of the filter membrane a smooth geometry that fits well to the artery wall Such a nitinol wire for shape control can be combined with a more flexible, but stronger fiber, which is used to protect the membrane against incidental overload, crack propagation or any of the described problems in non-reinforced membranes. Orientation and amount of the reinforcement fibers are not limited and vary with the application.

In figure 5 a distal filter 50 is given, with a conical shaped filter membrane 51, attached to the same proximal wire frame 20 as in figures 2- 4. In this example, however, the membrane is not dipped directly to the nitinol frame. It is attached by guiding for example the reinforcement fiber 52 from the distal end 53 under an angle with the cone surface until it reaches the nitinol struts 27 at points 29, than wrapped around these struts at points 29 and guided back to the distal tip with a reverse angle. Arrows in the drawing show how fiber 52 runs back and forth. By this method the use of knots at the fiber-nitinol connection is redundant and the safety is further increased, because the filter can never detach from the frame. The pattern with crossing reinforcement fibers gives the filter membrane different elastic properties and gives the benefit of an improved, but limited axial elasticity. The pattern of filter holes, preferably cut by laser, can be made between the fiber zones to stay away from damaging the fibers. However, if the pattern of reinforcement fibers is very fine, the holes may just be cut without looking at the position of these fibers. There will than still be enough reinforcement left, just because

adjacent crossing, parallel or angled uncut fibers can take over some forces via the embedding material of the membrane itself.

The cone design has the following advantages. If this filter has a maximum diameter of 8 mm and if it is placed in an artery of 8mm diameter, all holes will be free from the artery wall and blood can flow through all holes. As soon as particles of debris, like emboli, are entrapped, they will tend to collect at the most distal tip, leaving the more proximal holes open. The surface area of the flanges of the cone relates to the cross section area of the artery as the length of the cone edge from base to tip relates to the radius of the artery. Preferably, the accumulated surface area of the holes should be at least equal to the cross section area of the artery in order to guarantee an almost undistorted blood flow. This is the case if the relation between the total surface area of cone surface to total accumulated hole surface area is smaller than the relation between cone surface area and cross section area of the artery. For an 8mm artery a total amount of 6400 holes with 100microns diameter is needed for a same surface area. Of course the type of flow through small 100micron holes is different from the undistorted flow of an open artery. However, because the wall thickness of a reinforced membrane according to thius invention can be extremely small, the length of a hole (for example only 5 microns) ensures a much better flow than compared to a 100 micron hole in a thick membrane. A filter made in conical shape will also have enough free holes if it is used in arteries with smaller diameter. The holes that touch the artery wall will not anymore contribute to the flow, but the remaining free holes still have the same surface area as the actual cross section of the (smaller) artery. Filters according to this invention are so much more flexible than existing filters, that they can be made longer without creating problems in strong curves. Therefore they can have more storage capacity for emboli.

If the reinforced membrane and the filter frame are mounted to each other without overlap, like in figure 5, it may be clear that the collapsed diameter can be made smaller than in the case of for example figure 4. Here, at a specific cross section of the nitinol frame near the attachment points 29, the nitinol, the membrane, the fibers and a central guide wire are all taking their part of the available cross section in the delivery sheath. It depends on the demands if this is allowable, or that a design is chosen without overlap, where frame and membrane are separated by the fiber hinges, thus reducing the size.

The construction of nitinol frame 20 has certain advantages. The production of the frame is very simple, the guide wire is kept in the center, and the filter can be pushed out of the delivery sheath, eventually with the help of additional pull force through the reinforced membrane. Upon removal of the filter the longitudinal spokes 26 of frame 20 just have to pull the struts 27 of the zigzag section into a removal sheath. However, such a frame can also have some disadvantages. In strongly curved arteries the guide wire will bend and it will cause forces that may deform the zigzag struts. Eventually the contact with the wall of the artery is not optimal then, which is undesirable. Another disadvantage is that axial movements of the guide wire, for example caused by the angioplasty/stenting procedure will influence the position of the filter. It would be better if the guide wire could move freely over at least a certain axial length plus in radial and tangential direction within the entire cross section of the filter, without exerting any force on the expanded frame. In figures 6-9 an embodiment with such a free movable guide wire is disclosed.

Figure 6 shows a filter 60 that is constructed in such a way that it is delivered from a delivery sheath by pulling it out, in stead of pushing. After the procedure it is removed by pulling it into a removal sheath as well. The pull forces are applied in both directions by moving the guide wire in axial direction relative to the sheath. Guide wire 61 runs through the filter and ends at distal section 62. At the guide wire are stops 63 and 64, that have a larger diameter than the guide wire itself. These stops are connected tightly to the wire by any known technique. At the distal tip of the filter 60 a ring 65 is mounted, where the guide wire can slide through freely, until stop 63 touches this ring 65. At the proximal side of stop 64 a second slide ring 66 is mounted around guide wire 61. Slide rings 65 and 66 have been given a smooth shape with rounded edges to let the move easily in the sheaths and in the artery. The filter membrane 70 is connected directly to slide ring 65 and reinforcement wires 71 are also attached tightly to this ring. At the other side reinforcement wires 71 are connected to expandable frame 80 at connection points 81, eventually together with the membrane material itself. Expandable frame 80 is provided with points of attachment 82 at its proximal side, which are needed to pull the frame back into a removal sheath. Fibers 83 are connected to these points 82 and run to the proximal slide ring 66, onto which they are also tightly attached. If the guide wire is moved through the filter in proximal direction, stop 64 will move freely over a distance X1 before it touches slide ring 66 and fibers 83 become stretched. If the guide wire is moved through the filter in distal direction, stop 63 will move freely over a distance X2 before it touches slide ring 65. Fibers 83 will hang free than, because there is no axial force on slide ring 66. This means, when the filter has been placed in an artery, that the guide wire can move freely in the cross section area of the filter frame in both radial and tangential direction without exerting any forces onto this frame. Further the guide wire can also move back and

forth over a total distance (X=X1+X2) in longitudinal direction relative to the filter, before it influences its shape or axial position in the artery. Distance X can be enlarged by choosing the distance between fixed stops 63 and 64. If one of these stops is removed distance X is maximized. Of course the distal end section 62 of guide wire 61 must then be long enough to prevent that slide ring 65 disengages from the guide wire tip.
With the construction of slide rings 65 and 66 on guide wire 61 this guide wire can be rotated around its length axis without influence to the position and shape of the filter and its frame. All these degrees of freedom enable the operator to use guide wire 61 for the angioplasty/stenting procedure without influencing the shape and position of the distal filter. This is extremely important. Further this design shortens the length of the nitinol frame and thus it makes the filter more flexible and easier usable in strongly bent arteries and arteries with limited parking space for the filter. In a strongly curved artery the guide wire 61 may even touch the inner wall of frame 80, without exerting relevant forces to the filter. Even with such a strongly bent guide wire the filter will still maintain its full contact with the artery wall and guarantee a safe functioning of the device for a wide range of artery diameters and geometries. As can be seen if figure 6 is compared with figures 4 and 5, the design of figure 6 gives a much smaller proximal surface of the expanded frame. In figures 2-5 the nitinol spokes 26 and the proximal side of tube section 25 have a certain surface area that reduces blood flow. This surface area is much smaller in figure 6, because only a few thin fibers 83 are hanging in the blood flow. Another advantage is that debris in the blood will less likely adhere to the thin fibers than to the proximal side of parts 25 and 26. Of course an additional treatment of these fibers to reduce the tendency of blood cells to adhere to these fibers is helpful and is a part of this invention as well. The material for these fibers can be of any kind, and they can for example made of the same materials as the reinforcement wires for the filter membrane. An example would be a composite fiber made of a nitinol core, surrounded by a multifiber ultra high molecular weight highly oriented polymer. The nitinol can be used to give some shape control to the wire, for example to prevent that adjacent fibers get entangled. The polymer multifilament enables besides high strength and low strain the embedding with for example anti-thrombogenic agents.

In figure 7 the filter of figure 6 is shown while it is being delivered from a delivery sheath 90. This sheath has a wall 91 and a distal end 92. At the proximal side of the guide wire 61 a pushing force F is applied into distal direction, while sheath 90 is pulled back into proximal direction. Stop 63 on guide wire 61 is now in direct contact with slide ring 65, and force F is brought over by this ring to the reinforcement fibers 71 of the filter membrane 70. By the resulting pulling force in the filter membrane plus fibers 71 the filter membrane is stretched and this pulling force is brought over to the collapsed frame 80 via connection points 81. Frame and filter membrane will easily slide out of the sheath by this pulling force, followed by the unloaded fibers 83 and slide ring 66. As can be seen the proximal section 82 of frame 80, where the fibers 83 are attached to, is slightly bent inwards to create a conical proximal side of frame 80.

Figure 8 shows the filter while it is removed by means of removal sheath 100. Removal sheath 100 has a wall 93 and a distal end 94. At distal end 94 the removal sheath may have a flared end section 95, like in insert figure 8a, a tapered wall 96 like in insert figure 8b or a combination thereof. This distal end must enable the retrieval of the filter into the lumen of sheath 100 by a pulling force, which is applied to the proximal end of guide wire 61 while sheath 100 is moved into distal direction. The tapered proximal side 82 of the frame also helps to move the frame into the removal sheath. The force F1, applied to guide wire 61, is brought over by stop 64 to slide ring 66, which distributes the force to fibers 83 that are now pulling to the proximal side 82 of frame 80. The wire ends are attached by any technique that is available, for example by putting them through the respective holes 84, and secure them by a knot 85 on the inside surface of the frame. The proximal tips 86 have been made in such a way that they are slightly curved inside with a conical top angle that is larger than the top angle of the cone, described by the stretched fibers 83, just before the parts 86 enter into removal sheath 93. This is done to prevent that these proximal sections get stuck at the distal end 94 of the removal sheath. With the tapered shape of frame 80 the tension force in fibers 83 will easily make it possible to slide the removal sheath over the frame until it is completely covered by this sheath. Filter membrane 70, eventually filled with emboli debris, does not have to be pulled into this sheath completely. It can hang at the distal end 94, while the whole device is removed from the artery.

Figure 9a and 9b show an alternative embodiment 110 of the filter frame, in its expanded and collapsed shape respectively. The frame is now not made as a series of full unit cells, like in figures 6-8, but as half unit cells, connected in a zigzag-pattern. Here again the proximal side 112 is tapered with curved tips 116 and it has attachment holes 114 for the fibers.

The fact that the filter frame does not anymore have to be delivered with pushing force in its struts enables a further downscaling of these struts and thus a miniaturization of the delivery profile of the device. This is also

enhanced by the fact that the guide wire does not influence the shape and position of the filter upon angioplasty and stenting, so the frame itself can now also be made lighter.

A removable frame as disclosed in figures 6-9 may not only be used in application of filters. It can also be used as a removable temporary stent, dilator, reamer, occlusion device for main artery or side artery, a housing for a graft, a valve, a delivery platform for drugs, radiation or gene therapy or any other device that has to be placed and removed after some time. Applications are not restricted to arteries, but are meant for all body lumens. All these examples are meant to be a part of this invention as well.

Objects of the invention

It is an object of the invention that the thickness of a membrane with improved flexibility for use in a human body is minimized by the use of a composite material, comprising a thin membrane layer and a reinforcement material to ensure that it keeps enough strength or enable a proper attachment.

It is also an object of the invention that the membrane is attached to a frame to bring and hold said reinforced membrane in the desired shape.

Another object of the invention is that the frame is used to collapse or expand the reinforced membrane.

It is further another object of the invention that the reinforced membrane contains a pattern of holes to let body fluid through, while particles above a certain critical size are not allowed to flow through.

In yet another object of the invention the frame and reinforced membrane are used as a blood filter to prevent emboli above a given size to pass through the device, while the normal blood flow remains intact.

It is also an object of the invention that the blood filter according to this invention is used for distal protection in medical procedures comprising angioplasty and stenting.

Another object of the invention is that the reinforced filter membrane is used outside a patient's body.

Still another object of the invention is that the reinforcement fibers have a relatively high tensile stress and modulus of elasticity, compared to the material of the membrane itself.

It is further another object of the invention that the reinforcement fibers are relatively flexible upon bending.

Another object of the invention is that the reinforcement fibers have such properties that they are suitable to be used to bring and hold the membrane into a desired shape.

Of course it is also an object of the invention that reinforcement fibers of different types are used in the same product, comprising the use of fibers for shape control combined with fibers with high tensile strength.

It is an object of the invention that the reinforcement fibers can be made of a mono-filament or multi-filament and that they can have all kinds of cross sections and orientations.

It is also an object of the invention that the reinforcement wires are coated in a polymer to enhance the adhesion to the membrane material, including the coating with the same polymer.

Another object of the invention is that the coated reinforcement wires are glued to the membrane with a solvent for the given membrane material.

Another object of the invention is that the material, used for the membrane, includes but is not limited to all polymers, organic tissue and tissue from human or animal origin.

It is also an object of the invention that the membrane itself is made as a mesh.

Still another object of the invention is that the material for the reinforcement fibers includes all known materials, comprising carbon, glass, metals, metal alloys, for example nitinol, polymers, including ultra high molecular weight highly oriented polymers or combinations thereof.

It is further another object of the invention that the reinforcement wires can be attached to or in the membrane and to the frame by means of any known technique, including the use of dipping, spraying, welding, glue, stitching, sewing, pressing, heat, light and knotting.

Another object of the invention is that the reinforcement fibers are an integral part of the frame.

It is also an object of the invention that the sites of attachment of reinforcement fibers to the frame act as hinges to increase the flexibility.

It is further another object of the invention that the fibers can stop crack propagation through the membrane and prevent detachment of (parts of) the membrane.

It is an object of the invention that the fibers are distributed over the membrane surface in a specific designed pattern or in a random pattern.

It is also an object of the invention that the holes in the membrane are distributed over the membrane surface in a specific designed pattern or in a random pattern, even if they cut through the reinforcement fibers.

Another object of the invention is that the use of reinforcement fibers makes it possible to reduce the membrane thickness so much that the flow resistance through the holes in the membrane is minimized.

In yet another object of the invention the use of reinforcement fibers makes it possible to reduce the membrane thickness so much that the flow resistance through the membrane wall becomes so small, that it can act as a semi-permeable membrane.

Another object of the invention is the method that comprises preparing a mold of a material with a melting point well below the temperature where the membrane material is damaged, covering the mold with an intermediate material that allows the creation of a membrane surface on it, creating a membrane surface, providing the reinforcement fibers, covering the fibers with another layer of membrane surface, removing the mold by melting or solving and removing the covering of said intermediate material from the membrane surface.

Still another object of the invention is that the mold is made of a material that dissolves in a liquid or that it is made of a sheath, filled with fine solid grains and then vacuum sealed.

Another object of the invention is that the mold is made of an expandable or inflatable structure, which can be removed after dipping but before use.

It is further another object of the invention that the surface of the membrane filter may be coated with some additional material that improves the properties, for example the biocompatibility, drugs release or any other desired property, which the membrane itself does not offer.

It is within the scope of the invention that any material or any combination of materials can be used in any configuration to apply a pattern of reinforcement fibers to the membrane and to the frame.

Still another object of the invention is that the reinforced membranes can also be used for parts of catheters, like for example inflatable parts, balloon pumps, replacement of body tissues, repair of body parts and functional parts like artificial valves and membranes.

Another object of the invention is a filter with enlarged free surface area at the proximal side of the expanded frame, in order to prevent obstruction of the blood flow and to reduce the surface area, occupied by the filter materials at this proximal side, where debris or platelets might adhere to said proximal surface.

It is within the scope of the invention that the proximal section of the expandable frame is connected to the guide wire by means of tension or pulling fibers, which can pull the frame into a removal sheath in order to retrieve it from the lumen of the patient's body.

It is within the scope of the invention that the distal section of the expandable frame is connected to the guide wire by means of tension or pulling fibers, which can pull the frame out of a delivery sheath in order to place it in a lumen of the patient's body.

Still another object of the invention is that the guide wire has at least one section with larger diameter that can be used to apply a force in proximal or distal direction to slide rings which are connected to the filter by means of reinforcement or pulling fibers, membrane material or combinations thereof.

It is also an object of the invention that the pulling fibers are directly attached to a slide ring at one side and to the expandable frame at the other side.

Still another object of the invention is that the proximal section of the removable frame is made slightly tapered to prevent removal problems while the frame is retrieved into the sheath.

It is also an object of the invention that the pulling fibers for retrieval are made of materials comprising all the disclosed materials for reinforcement fibers and combinations thereof.

Another object of the invention is that the pulling fibers are coated with or embedded in a passive or active biocompatible material that prevents the adherence of emboli or platelets, or releases active drugs to the patient's body.

It is within the scope of the invention that the distal end of the guide wire is provided with a pressure sensing tip for continuous monitoring of the blood pressure.

Still another object of the invention is that the guide wire can move freely in the cross section area of the expanded frame in axial, radial and tangential direction as well as upon rotation around its length axis, without influencing the position and shape of the frame.

Another object of the invention is that a filter according to this disclosure is used in a double filter system as described in US 2001/0044634.

It is also an object of the invention that one filter system according this disclosure can be used in body lumens of a wide range of sizes and curvatures.

It is within the scope of the invention that one or each of the disclosed embodiments can also be used as a removable temporary stent, dilator, reamer, occlusion device for main artery or side artery, a housing for a graft, a valve, a delivery platform for drugs, radiation or gene therapy or any other device that has to be placed and removed after some time. Applications are not restricted to arteries, but are meant for all body lumens.

It will be obvious to those skilled in the art having regard to this disclosure that other modifications of this invention beyond these embodiments specifically described here may be made without departing from the spirit of the invention. Accordingly, such modifications are considered within the scope of the invention as limited solely by the appended claims.

Claims (to be filed later).

Fig. 1

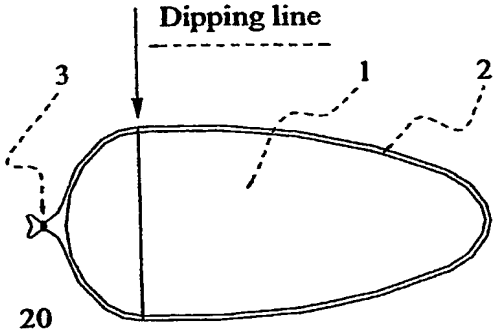

Fig. 2

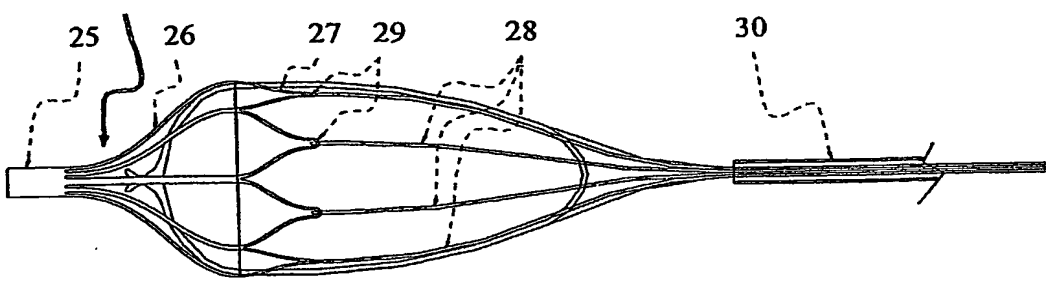

Fig. 3

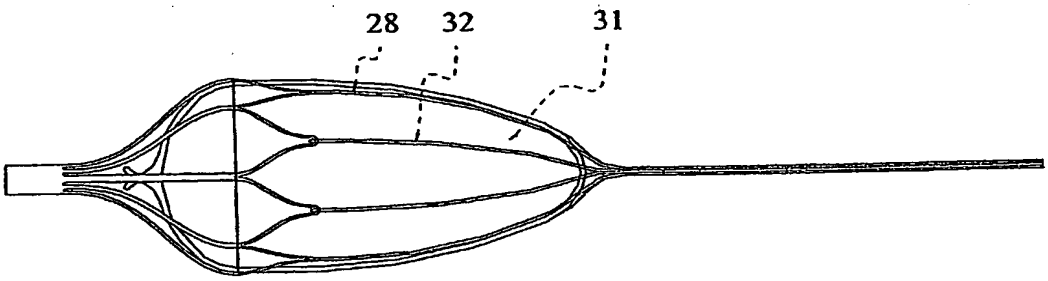

Fig. 4

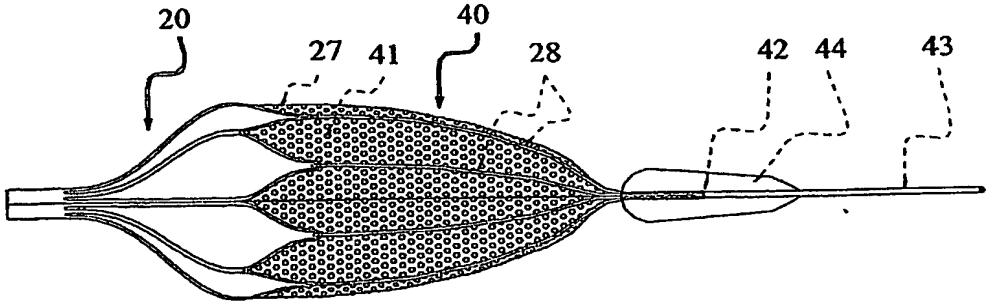

Fig. 5

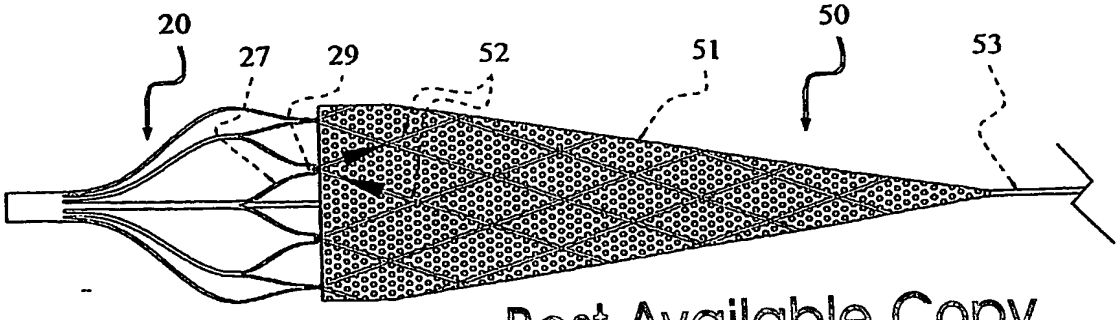

Fig. 6

Fig. 7

Fig. 8

Fig. 9a

Fig. 9b

Fig. 8b

Fig. 8a